

## **REMARKS/ARGUMENTS**

In the Examiner's November 6, 2003 Office Action, the Examiner first stated that the trademark LUMONICS HY 400 should be capitalized wherever it appears and accompanied by the generic terminology. In response to the Examiner's statement, Applicant has amended the specification to comply with the proper use of the trademark LUMONICS.

The Examiner next objected to the disclosure due to various informalities outlined in pages 2-3 of the Examiner's Office Action. In response to the Examiner's objection, Applicant has amended the specification in accordance with the Examiner's suggestions.

Next, the Examiner rejected claims 34, 41, 49 and 50 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. At this time, Applicant has cancelled claims 34, 41, 43, 47, and 49-50, without prejudice or disclaimer, which are directed to the Examiner's rejection.

The Examiner also rejected claims 31 - 50 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In response to the Examiner's rejection, Applicant has amended claim 31, line 1 to delete the term "certain" and has followed up by making that same amendment in the remaining claims. Applicant has also amended claim 31 to delete "constant amount" and insert in its place "certain amount" in referring to the internal reference species. Applicant has also made this same amendment throughout the remaining claims. With respect to the Examiner's statement that the phrase "if the specimen does not already contain one" is vague and indefinite in claim 31, Applicant directs the Examiner to page 25 of Applicant's specification in which it is clear that the specimen may already inherently contain an internal reference standard. Further, with respect to the Examiner's statement that the phrase "effective amount" is vague and indefinite in claim 32, Applicant directs the Examiner to page 13 of the specification where an "effective amount" is defined as "that amount necessary to capture an adequate quantity of the analyte (and internal reference species where relevant) to achieve the desired result." In claim 32 it is clear that the desired result is to produce a post-combination affinity reagent with an unbound remainder of the specimen. With respect to the Examiner's statement that the phrase "an unbound remainder" is vague and indefinite in claim 32, Applicant has amended this phrase to state "unbound remainder of the specimen". Finally with respect to the Examiner's statement that claim 33 lacks antecedent basis with respect to the phrase "the unique mass-to-charge ratio of the IRS", Applicant has amended claim 33 and like claims to delete "the" and insert "a" in its

place.

Claims 31 and 37 stand rejected under 35 U.S.C. §102(b) as being anticipated by Gaskell et al. (Immunoabsorption to Improve Gas Chromatography/High-Resolution Mass Spectrometry of Estradiol-17B in Plasma, Clin. Chem. 29/4, 677-680 (1983)). In particular, the Examiner states that Gaskell et al. discloses a method for detecting at least one analyte in which an internal standard is added to the sample containing the analyte. The Examiner further states that Gaskell discloses capturing and isolating the analyte and internal standard with an affinity reagent and that this extract containing the analyte and internal standard is analyzed by GC-MS. Finally, the Examiner states that Gaskell discloses that a standard curve is used for the quantitation of the analyte and internal standard and that the standard curve was established by analysis of derivatized standard mixtures. Applicant respectfully traverses this rejection.

Gaskell is specifically directed to establishing fractionation procedures that complement the specificity of gas chromatography-mass spectrometry (GC-MS) detection. Applicant's claimed methods do not require gas chromatography either before, or in combination with, mass spectrometry in order to achieve detection. Accordingly, Gaskell cannot anticipate Applicant's claimed invention.

Claims 31-34, 37-39, 41 and 44-47 stand rejected under 35 U.S.C. §102(a) as being anticipated by Nelson et al. (Mass Spectrometric Immunoassay, Analytical Chemistry 1995, 67, 1153-1158). Applicant respectfully traverses this rejection.

Under 35 U.S.C. §102(a), a person is entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent. The Nelson journal article cited by the Examiner does not constitute a description of the invention in a printed publication before the invention was made by Applicants in that Applicants are the authors of the journal article and Applicants conceived their invention before the publication of their journal article.

It should be noted that Mr. Allan L. Bieber, who is also noted as an author of the Nelson reference did not take part in the conception of the subject matter disclosed and claimed in the instant application and instead provided materials for carrying out and performing experimental protocols that were determined by the inventors listed in the subject application. Mr. Bieber's declaration attesting to these facts is attached hereto. Accordingly, claims 31-34, 37-39, 41 and 44-47 are not anticipated by Nelson and Applicants respectfully request the withdrawal of the

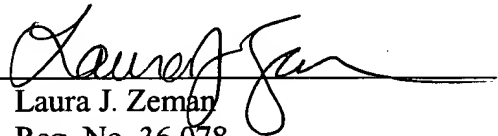
Examiner's rejection under 35 U.S.C. §102(a).

Claims 35, 36, 40, 43 and 48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Nelson* in view of *Papac et al.* (Direct analysis of Affinity-Bound analytes by MALDI/TOF MS, Analytical Chemistry 194, 66, 2609-2613) (hereinafter "*Papac*"). Claims 34, 41, 49 and 50 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Nelson* in view of *Raybuck et al.*, U.S. Patent No. 5,833,927, issued November 10, 1998 (hereinafter "*Raybuck*").

As previously pointed out above with reference to the Examiner's 35 U.S.C. Sec. 102(a) rejection, the *Nelson* reference does not constitute prior art for purposes of the Examiner's 35 U.S.C. Sec. 103(a) rejections because the *Nelson* publication was authored by the inventors and the inventors conceived of the invention prior to the publication. Accordingly, if the *Nelson* reference is removed from the Examiner's 35 U.S.C. Sec. 103(a) rejections, it would clearly not have been obvious to one of ordinary skill in the art to arrive at Applicants' claimed invention. Therefore, Applicants respectfully request the withdrawal of the Examiner's 35 U.S.C. Sec. 103(a) rejections.

In view of the foregoing, Applicants respectfully submit that all of the pending claims fully comply with 35 U.S.C. §112 and are allowable over the prior art of record. Reconsideration of the application and allowance of all pending claims is earnestly solicited. Should the Examiner wish to discuss any of the above in greater detail or deem that further amendments should be made to improve the form of the claims, then the Examiner is invited to telephone the undersigned at the Examiner's convenience.

Respectfully submitted,

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